Exhibit 20 (part 2)

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Strengthening the FDA's Ability to Carry Out its Mission

3.1 Congress should assure adequate capacity and scientific expertise at the FDA by performing the following:

1. Require the FDA to conduct an organizational review process to identify gaps in scientific expertise, capacity to carry out various aspects of its mission, and opportunities for streamlining and using existing resources more efficiently.
2. Require FDA, working with HHS and the Office of Personnel Management, to modernize human resources practices and systems to address gaps in scientific expertise and capacity, by performing the following and reporting to Congress on progress, within 12 months:
    a. Reviewing and improving recruiting, hiring, and retention strategies;
    b. Implementing direct hiring authority;
    c. Allowing the use of qualified blind trusts or other appropriate mechanisms to address conflict-of-interest concerns;
    d. Exploring and improving personnel policies that support appropriate turnover; and
    e. Implementing additional exemptions from standard federal agency hiring policies (including increasing the number of employees that can exceed federal salary compensation caps).
3. Eliminate barriers that prevent FDA staff from attending scientific conferences and meetings, which are crucial to helping them keep up with the latest scientific developments.
4. Encourage FDA to expand its partnerships with academic

institutions to raise awareness of the opportunities at the FDA and build a pipeline of talented graduates who can establish a career at the agency.

5. Encourage FDA to improve its IT infrastructure to support knowledge management and sharing, workflow management, and more effective communications across reviewers and centers, as well as with sponsors.
6. Create for FDA a waiver of the OMB Paperwork Reduction Act to further FDA's ability to more readily collect information from industry, academia, patient groups, and other experts and stakeholders through voluntary surveys and questionnaires, to rapidly expand knowledge and insights.

3.2 Congress should encourage the effective use of public-private partnerships at the FDA by performing the following:

1. Reconfirm and encourage the FDA to use its existing authority to use partners and trusted intermediaries to augment FDA internal resources, particularly for novel or complex technologies that may be outside of the FDA's normal expertise.
2. Require the FDA to monitor, evaluate, and report on the outcomes and effectiveness of existing public-private partnerships to determine whether additional investment in these programs and/or further coordination and accountability associated with such programs is warranted, as well as whether outdated or ineffective public-private partnerships should be phased out.
3. Support the launch of a study to both assess current conflict of interest policies associated with advisory groups and develop recommendations that both effectively address conflict of interest concerns and enable FDA to gain input from a broad and representative set of individuals including patients, clinicians, and researchers.

3.3 Congress should improve the FDA's internal review processes by performing the following:

1. Direct FDA to both conduct and implement strategies in response to an organizational study of its review and approval processes; this study should evaluate review times, identify root causes of delays, identify best practices, and recommend measurable goals and actions to support faster turnaround times. As part of this effort, FDA should conduct a best practices study of review divisions to identify best practices that can be applied across divisions.
2. Direct FDA to develop an inter-agency education and training program to implement best practices across centers and divisions.
3. Direct FDA to establish a monitoring system to track and report progress against implementation goals and impact on drug and device review times.

Increasing Investment in Medical Products to Address Unmet and Public Health Needs

4.1 Congress should accelerate the development and approval of antibiotics by performing the following:

1. Require FDA to establish a program to expedite the approval of certain antibacterial and antifungal drugs for use in limited populations of patients at the request of the sponsor, which includes the following:
    a. Requires prominent labeling of the limited population antibacterial and antifungal drugs that indicates it is for a limited and specific population and requires the sponsor to submit promotional materials to the FDA for approval; and
    b. Allows the FDA to remove labeling and promotion restrictions if the drug is approved for broader use.
2. Require FDA to publish guidance describing criteria, process, and other considerations for demonstrating the safety and effectiveness of antibacterial and antifungal drugs approved for use in limited populations.
3. Require the FDA to publish an assessment of the program, hold a public meeting, and consider expansion of the limited use pathway and program beyond antibacterial and antifungal drugs.

4.2 Congress should improve processes for early patient access to medical products by performing the following:

1. Require sponsors to make their policies on expanded access during clinical trials publicly available, including procedures for requests, qualification criteria, and a single point of contact.

2. Require FDA to finalize guidance regarding how it interprets and uses adverse drug event data resulting from drug use under expanded access programs.

4.3 Congress should increase incentives for the development of medical products with unmet medical needs by creating a new regulatory pathway for dormant therapies, by performing the following:

1. Give the FDA the authority to designate a new treatment as a "dormant therapy" if intended to treat an unmet medical need. A dormant therapy must not contain active ingredients that have been previously approved by the FDA.
2. Determine a fixed period of protection from generic and biosimilar competition for dormant therapies.
3. Require sponsors of approved dormant therapies designation to waive certain rights to patents of the approved dormant therapy at the end of the protection period.

Conclusion

Congress has demonstrated significant bipartisan leadership in advancing proposals that will accelerate the development and delivery of both safe and effective drugs and devices to the American people.

The policy recommendations included in this report will significantly advance medical innovation and support patients in gaining timely access to treatments that can cure their diseases, improve their conditions, and promote their general health and wellbeing.

End Notes

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